OCT 2 4 2003

K032482

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

(As required by 21 CFR 807.92)

Trade Name:	HemoPoint® H2 Hemoglobin Measurement System
Common/Classification Name:	Automated Hemoglobin System
Device Classification:	Class: II CFR: 21 CFR 864.5620 Product Code: GKR
Manufacturer:	Stanbio Laboratory 1261 North Main Street Boerne, Texas 78006

Device Description / Procedure Principle:
The HemoPoint® H2 Hemoglobin Measurement System is comprised of a HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes.

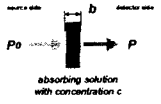
The recognized reference method for tHb determination (tHb = total hemoglobin) is the cyanmethemoglobin method, which is also known as the cyanhemoglobin method. The blood sample is diluted 1:251 with a reagent buffering solution. Here the erythrocytes are hemolysed and the bivalent iron in oxy- and desoxyhemoglobin are oxidised by the reagent potassium hexacyanoferrate (III) to trivalent iron and so converted to methemoglobin. Together with cyanide ions, which are also contained in the reagents, the methemoglobin forms a stable, colored complex, namely cyanmethemoglobin. This has a wide absorption maximum at 540 nm. This absorption is proportional to the tHb concentration.

In 1966, Vanzetti suggested to replace KCN by NaN_3 and thus was able to reduce the toxicity of the reagent mixture considerably.

Vanzetti's method is also known as the azide methemogobin method. A modified azide methemoglobin method is used in the HemoPoint® H2 system.

In the *HemoPoint® H2*, however, the use of microcuvettes with short light pathways makes it possible to analyze undiluted blood. The filled cuvette is inserted into the *HemoPoint® H2* photometer, the color produced by the chemical reaction in the cuvette is measured, and the Hb level is calculated and displayed.

In the *HemoPoint® H2* photometer the light transmitted through the cuvette sample is measured.



Principle of photometric transmitted light measurement.

P_0: 100 % - light intensity, P: remaining light intensity, b: distance through the solution

For this purpose, light is directed through the blood sample and the transmission T is measured. From the amount of light absorbed by the sample, the concentration of the hemoglobin in the cuvette can be calculated using Lambert-Beers Law.

Light emitting diodes (LED's) are used as light sources and a photodiode to detect the light. The light emitting diodes utilize the central wavelengths 570 nm (for measurement) and 880 nm (for turbidity compensation).

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Intended Use:

The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary blood.

The microcuvettes part number 3010-100 are indicated for use in the HemoPoint® H2 Hemoglobin Measurement System and the Hemocue® measurement system. The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.

Estimation of hematocrit as a function of Hemoglobin is performed for normal hemoglobin ranges only (120 to 180 g/L or 12.0 to 18.0 g/dL). The estimated hematocrit is not indicative of disease states such as anemia and abnormal values and will not be reported.

For In Vitro Diagnostic Use Only

Comparison To Predicate Device:

Precision:

Within-run imprecision HemoPoint® H2 System and HemoPoint® H2 Cuvettes on HemoCue Device ≤ 2%

	HemoPoint® H2 cuvette measured in HemoPoint® H2 device	**HemoPoint® H2 measured in HemoCue device**
Hemoglobin/high (17.3 g/dL):		
Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.111 g/dL, CV 0.6 %	S_{wr} 0.103 g/dL, CV 0.6 %
Total Precision (NCCLS EP5-A):	S_T 0.207 g/dL, , CV 1.2 %	S_T 0.162 g/dL, CV 0.9 %
Hemoglobin/low (10.7 g/dL)		
Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.095 g/dL, CV 0,9 %	S_{wr} 0.068 g/dL, CV 0,6 %
Total Precision (NCCLS EP5-A):	S_T 0.114 g/dL, CV 1.1 %	S_T 0.086 g/dL, CV 0.8 %
Hemoglobin/normal (12.9 g/dL)		
Within-Run Precision (NCCLS EP5-A):	S_{wr} 0.084 g/dL, CV 0.7 %	S_{wr} 0.102 g/dL, CV 0.8 %
Total Precision (NCCLS EP5-A):	S_T 0.148 g/dL, CV 1.1 %	S_T 0.134 g/dL, CV 1.0 %
Between-Day Imprecision Single observation, 20 days	10.7 g/dL: SD 0.102 g/dL, CV 1.0 % 12.9 g/dL: SD 0.141 g/dL, CV 1.1 % 17.3 g/dL: SD 0.169 g/dL, CV 1.0 %	10.9 g/dL: SD 0.094 g/dL, CV 0.9 % 13.0 g/dL: SD 0.126 g/dL, CV 1.0 % 17.2 g/dL: SD 0.148 g/dL, CV 0.9 %

Correlation Study:

Correlation coefficient HemoPoint® H2 System compared to NCCLS H15-A3 reference method, venous blood: ≥ 0.98

Correlation coefficient HemoPoint® H2 cuvettes on HemoCue Device compared to HemoCue System, venous blood: ≥ 0.97

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS CONT'D

Experimental Data:

HemoPoint® H2 System: (HemoPoint® H2 cuvettes measured in HemoPoint® H2 device):

Regression line and correlation coefficients compared to NCCLS H15-A3 reference method (g/dL), venous blood (Summary from 4 Clinical Study Sites)	- Y= 0.023 + 1.006X - R=0.999 - N=174, duplicate measurements - Range 3.31 g/dL to 24.4 g/dL
Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites)	- Y= - 0.233 +1.001X - R=0.998 - N=286, duplicate measurements - Range 3.25 g/dL to 23.85 g/dL

HemoPoint® H2 cuvettes measured in HemoCue device[i]:

Regression line and correlation coefficients compared to HemoCue system (g/dL), venous blood, (Summary from 4 Clinical Study Sites)	- Y= 0.139 +986X - R=0.999 - N=286, duplicate measurements - Range 3.25 g/dL to 23.85 g/dL

Comparison to Predicate Device:

Specification	HemoPoint® H2	HemoCue	Comments
Instrument :	No. 1	No. 2	No.1 ←→ No. 2
Measurement range	0 – 25.6 g/dL	0 – 25.6 g/dL	equivalent
Specified range	0 – 25.6 g/dL	0 – 23.5 g/dL	equivalent
Specified accuracy	± 0.3 g/dL at ≈14 g/dL	± 0.3 g/dL at ≈14 g/dL	equivalent
Sample material	venous, arterial or capillary human blood	venous, arterial or capillary human blood	equivalent
Measuring time	Approximately 30 – 60 sec	Approximately 30 – 60 sec	measuring time depends on the concentration
Measuring units	mol/L, g/dL, g/L	mol/L, g/dL, g/L	equivalent
Calibration	against NCCLS reference method	against ICSH reference method	NCCLS is current version of the method
Method	Azidemethemoglobin method (Vanzetti)	Azidemethemoglobin method (Vanzetti)	equivalent

Conclusion / Substantial Equivalence:

The HemoPoint® H2 Hemoglobin Photometer and HemoPoint® H2 Cuvettes and the predicate devices, HemoCue B-Hemoglobin System with microcuvette are substantially equivalent based on design and function.

Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 4 2003

Mr. Kirk Johnson
QA/Regulatory Affairs Manager
Stanbio Laboratory
1261 North Main Street
Boerne, Texas 78006

Re: k032482
Trade/Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System
Regulation Number: 21 CFR § 864.5620
Regulation Name: Automated Hemoglobin System
Regulatory Class: II
Product Code: GKR
Dated: August 5, 2003
Received: August 12, 2003

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032482

Device Name: Stanbio Laboratory HemoPoint® Hemoglobin Measurement System

Indications for use:

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For In Vitro Diagnostic Use Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032482

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use ____

(Per 21 CFR801.109)

(Optional Format 1-2-96)